MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

MEDICAL RECORD

• Attach to NIH-2514-2, Consent to Participate in a Clinical Research Study

INSTITUTE: National Institute of Child Health and Human Devlopment

STUDY NUMBER: 00-CH-0160 PRINCIPAL INVESTIGATOR: Constantine Stratakis, M.D.

STUDY TITLE: Clinical and Molecular Analysis of ACTH-Independent Steroid Hormone Production in

Adrenocortical Tissue

Latest IRB Review: Continuing Review 7/23/04 Latest Amendment Approved: Amend D 4/8/03

Minor Patient Assent

Your parents have brought you to the National Institutes of Health, because you have a tumor in a part of the body called the "adrenal gland". We do not know what caused this tumor.

Read this paper and ask us questions about anything you do not understand. Then you and your parents decide if you wish to take part.

What we want to do

We want to find what caused your tumor, and whether this tumor can happen again in another person in your family.

We will ask you to come to our hospital at the National Institutes of Health (NIH). We will need to find out what kind of substances ("hormones") your tumor is making. In order to do this, we may need to do some blood and urine tests and get X-rays of parts of your body.

We will also do a test that was not done by your doctor: We will collect blood to get a substance called "DNA". DNA is the substance that contains the genes, that decides what runs in families ("inheritance"). Our DNA has all the information for how we look, and what diseases we may have. We will compare your DNA with that of your parents, brothers and sisters to see if there is anything about your genes that may be causing your tumor.

What we want you to do

- (1) Your parents and/or your pediatrician will need to tell us about any medical problems you may have. Anything they tell us will be kept private.
- (2) We will ask you to spend a number of days (usually, no more than two weeks) in the hospital to do the tests to find out what hormone your tumor is making, and to try to find out why it is being made.
- (3) We will need to examine your blood. To get your blood, we will stick a needle into your arm and take a small amount of blood (2 to 4 teaspoons) through the needle. That will only hurt for a minute. Then it will stop hurting. If you want, we can put a special cream on your arm one hour before blood drawing so that it won't hurt as much. A small plastic tube will remain in your arm and blood will be taken from it, so that we do not need to use a needle every time blood is taken from you.

PATIENT IDENTIFICATION

MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

NIH-2514-2 (4-97) P.A.: 09-25-0099

File in Section 4: Protocol Consent (4)

CONTINUATION SHEET for either:

MEDICAL RECORD

NIH 2514-1, Consent to Participate in A Clinical Research Study NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

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(4) We may need to do some special blood tests to find out what kind of tumor you have. These tests will be explained to you and your parents. For most of the tests, we will give you some medicine through the small plastic tube in your arm, and then blood will be taken out through the same tube. Sometimes people feel hot or dizzy when they get these medicines, but a nurse will be watching you to make sure you do not get sick.

- (5) We may need to take pictures of parts of your body, with the help of machines that we have in the hospital ("Department of Radiology"). In one of these tests (called "MRI-scan") you will be on a moving bed, and your body will be surrounded by a big tube. That will only last for about 30 minutes, but you will need to lie still for the time that the test lasts. The space inside the tube is very small; if you are frightened by it, someone can stay in the room and talk to you. Also the machine normally makes a loud ticking noise that may surprise you. If necessary, we will give you a medicine to make you sleep through the test. This medicine is given by a specialized nurse or doctor (an "anesthesiologist"), who will explain what will happen to you while you sleep.
- (6) We may take photographs of you that we will use in the future to look at the way you change as you grow.
- (7) Everything we find out will be explained to you and your parents. We will also find out if you have any other diseases or tumors. Because your adrenal tumor is making a hormone, it will probably need to be removed by surgery, but we will not do this until we talk about it with you, your parents and your doctor. If you and your parents want, this surgery will be done here at the NIH, and another doctor (the surgeon) will explain to you and your family about the surgery. If medicine is needed, we will discuss it with you and your family. If other treatment is needed that cannot be offered at the NIH, we will discuss with you and your parents where and how this treatment can be done. For example, "radiation" treatment is something that can be done for you but we can not do it here at the NIH (under this study).

What you have to decide about

We want you to understand what we will do, why we do it, and the things that will hurt. Ask us if there is anything you do not understand now or later.

If you agree to come to the hospital, be seen by our doctors and have blood tests, and the other tests needed to study your tumor, we will ask you to write your name on this piece of paper, beside the X. Writing your name here is the way of showing that you agree.

You do not have to do this, if you, or your parents do not want to. Do not write your name until you feel you understand what will happen. Even if you agree now, you and your parents can change your minds later. Just tell us that you do not wish to take part any longer.

EDICAL RECORD	MINOR PATIENT'S ASSE	NT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY
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I have had this s I agree to take p	tudy explained to me in a w art in this study.	ay that I understand, and I have had the chance to ask questions
Signature of Mind	or Patient:	Date:
Signature of Inve	estigator:	Date:

PATIENT IDENTIFICATION

MINOR PATIENT'S ASSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

NIH-2514-2 (4-97)

P.A.: 09-25-0099 **FAX TO: (301) 480-3126**

File in Section 4: Protocol Consent